UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 28 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Dear Antimicrobial Registrant:

On May 8, 2013, the EPA published a final rule amending 40 CFR Part 158, the section of the regulations setting forth the data requirements that support an application to register a pesticide product. This final rule, which is codified as 40 CFR Part 158 Subpart W (158W), contains the data requirements specifically applicable to antimicrobial pesticides. The rule was effective starting on July 8, 2013. This letter is being issued in order to summarize how the Agency has been implementing 158W with respect to existing registered antimicrobial pesticides, as well as new and pending antimicrobial pesticide applications. A more detailed explanation of the Agency's position with respect to implementation may be found in the preamble to the final rule and the accompanying response to comments document, both of which are available at www.regulations.gov in Docket ID # EPA-HQ-OPP-2008-0110. Furthermore, the Agency is available to assist the registrant community as this new rule continues to be implemented.

Changes in Data Requirements

158W codified data requirements for antimicrobial pesticides that the Agency had already been requiring consistently on a case-by-case basis, established new data requirements for antimicrobial pesticides, and changed some existing data requirements. Changes to existing data requirements include changing from conditionally-required to required, changing the number of test species, or expanding the number of use patterns for which the test is required. In addition, the rule established twelve use patterns to differentiate the data needed for the different types of antimicrobial pesticides. The use patterns, combined with exposure patterns, delineate the requirements.

There will be some registration actions for which changes in data requirements will affect the PRIA category for a submission. For example, uses that were previously termed "indoor" uses in 40 CFR Part 161 had limited environmental fate and ecotoxicity data requirements. Now some of these uses may have more extensive environmental fate and ecotoxicity data requirements and would necessitate a different PRIA code.

The Agency is developing a guidance document called the Antimicrobial Pesticide Use Site Index (USI) that will serve as a compilation of existing use sites and will identify how each use site fits within the twelve use patterns established in 158W. The guidance document will

serve to assist prospective registrants with the application requirements by making it easier for them to identify which data are necessary to register their product(s). We intend to take comment for 30 days on the USI in the next few months and then issue it shortly thereafter. A Federal Register Notice (FRN) and OPP Update will announce the opening of a new docket for the comments.

The Agency has a mandate to ensure that products containing each pesticide active ingredient continue to meet the statutory standard for protection of human health and the environment. As science has advanced and laws have changed, the type of data necessary to evaluate the potential effects of pesticides has evolved. Thus, the Agency may find it necessary to call in data as each active ingredient is evaluated under the Registration Review program. As part of the Registration Review program, the Agency will evaluate whether new data are needed in the context of, but not limited to, the requirements in 158W. Because the Agency will evaluate the need for new data when each active ingredient is assessed under the Registration Review program, the Agency does not intend to conduct this generic evaluation for new products or applications to amend existing products that are covered in PRIA3 fee category Table 9 – Antimicrobials Division – New products and Amendments.

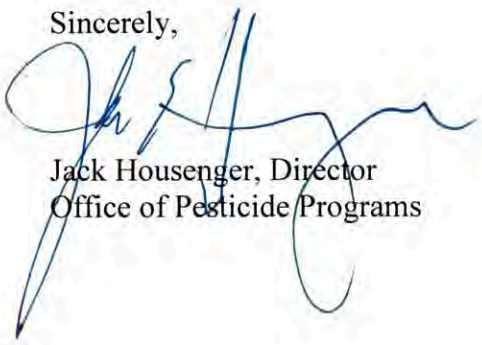
The Agency recognizes that during early implementation of 158W not all new application packages may have all of the newly-required data. As a result, conditional registrations under FIFRA section 3(c)(7) may be appropriate in some cases, particularly for new active ingredients and new uses. In determining whether a pesticide product may be registered "conditionally" in the absence of newly-required data, EPA must find that the proposed use will not significantly increase the risk of unreasonable adverse effects on the environment. If EPA can make that determination and the other elements for a conditional registration FIFRA section 3(c)(7) are met, then the new data could be required as a condition of registration. If EPA determines that a conditional registration is appropriate, the Agency will set a deadline for the submission of the required data. In some cases, EPA may not be able to make a registration decision or safety finding and the application may be denied or the applicant may choose to withdraw the application pending completion of the needed data.

Application packages submitted after the July 8, 2013, effective date of the new data regulation that do not contain all of the newly required data must be supported by adequate justification. The applicant should address the issue of timing (*i.e.*, why the data are not yet submitted and when the data can be submitted) with respect to any missing, newly-required data in their justification. Applications not containing required data or an adequate justification for missing data will be deemed incomplete and rejected under the 45/90 day preliminary technical screen under PRIA. EPA envisions that this early implementation period in which insufficient time was available to provide required data could extend up to 2 years and 6 months beyond the rule's effective date for applications in which a more time-intensive new study is missing. The time period could be less for other applications with less time-intensive missing studies.

Agency Support

The Office of Pesticide Programs Antimicrobials Division (AD) is committed to assisting the registrant community throughout the implementation of this regulation. AD plans to provide information and guidance on how EPA will evaluate potential exposure and risks of antimicrobial pesticides via recorded informational presentations to assist the regulated community in understanding this new rule. These presentations will be based on specific disciplines and use patterns, and AD would appreciate input as to which topics are of the highest priority to the registrants. We are planning to post 10-12 different recorded presentations on AD's website with the first postings starting this summer. AD also plans to provide guidance material to supplement the presentations as well as to meet with stakeholders to answer questions about the implementation of the rule, as needed. If you have questions or suggestions for the presentations, please contact Steven Weiss, Chief, Risk Assessment and Science Support Branch (703-308-8293). As always, AD's Product Managers are available to answer any of your questions regarding new application submissions or current registrations.

Sincerely,



Jack Housenger, Director
Office of Pesticide Programs